From:	CBER Complicheck
To:	DeMar, Maureen; CBER Complicheck; Kennedy, Niloofar
Cc:	Price, Gregory; He, Jie; Ertel, Donald; Trudel, Nicole
Subject:	RE: URGENT: Compliance Check for BLA 125771/0
Date:	Friday, February 17, 2023 3:42:54 PM
Attachments:	Endorsement_Biogen Inspection_PLI 125771-0_Dec 2022.pdf BLA 125771-0_02-16-2023_Inspection Related_Inspect.pdf

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- **Applicant Name:** Bioverativ Therapeutics, Inc.
- **Product Name:** Antihemophilic Factor (Recombinant), Fc-VWF-X TEN fusion Protein
- **License Number:** 2078
- **Address:**

  225 Second Avenue

  Waltham, MA 02451
- **Application #:** 125771/0
- **Projected Approval Date/Action Due Date: February 17, 2023/** February 28, 2023. Please complete today **February 17, 2023** targeted date.

Summary: efanesoctocog alfa for treatment of adults and children with Hemophilia A (congenital Factor VIII deficiency) for:
(1) Routine prophylaxis to reduce the frequency of bleeding episodes;
(2) On-demand treatment and control of bleeding episodes;
(3) Perioperative management of bleeding.

List only those manufacturing locations requiring inspection for an original application approval. List all manufacturing locations affected by the change(s) identified in a supplement:

Inspections:

(b) (4)

Waivers:

(b) (4)

(b) (4)

(b) (4)

(b) (4)

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(b) (4)

There are no ongoing or pending investigations or compliance actions with respect to the above facilities or their product(s). Therefore, the Office of Compliance and Biologics Quality, Division of Case Management does not object to the approval of this supplement.

Michele L. Forster, Ph.D.
Compliance Officer
CBER/OCBQ/DCM/BDDCB

From: DeMar, Maureen <Maureen.DeMar@fda.hhs.gov>
Sent: Friday, February 17, 2023 2:37 PM
To: CBER Complicheck <complicheck@fda.hhs.gov>
Cc: Price, Gregory <Gregory.Price@fda.hhs.gov>; He, Jie <Jie.He@fda.hhs.gov>; Ertel, Donald <Donald.Ertel@fda.hhs.gov>; Trudel, Nicole <Nicole.Trudel@fda.hhs.gov>; DeMar, Maureen <Maureen.DeMar@fda.hhs.gov>
Subject: URGENT: Compliance Check for BLA 125771/0
Importance: High

PLEASE EXPEDITE: a compliance check.

Please confirm receipt of this communication.

Kindly send your compliance check response to all on the email.

Please see attached PLI Waiver Memo.

PLI was conducted at the below (b) (4) (b) (4) from (b) (4)

The inspection was classified as VAI. Please find attached a copy of the signed Endorsement from eNspect."

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(b) (4)

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(b) (4)

(b) (4)

(b) (4)

Thank you,

Maureen DeMar, BSN, RN
Regulatory Project Manager

Center for Biologics Evaluation and Research
Office of Compliance and Biologics Quality
U.S. Food and Drug Administration
maureen.demar@fda.hhs.gov